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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,778	06/01/2005	Sangita Phadtare	PHADTARE1.1A	3527
1444 7590 01/11/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 01/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,778

Applicant(s)

PHADTARE ET AL.

Examiner

Hope A. Robinson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's election without traverse of Group VII (claims 14-15) is acknowledged.

Claim Disposition

2. Claims 1-13 and 16-25 have been canceled. Claims 14-15 are pending and are under examination.
3. The Amendments filed on October 18, 2007 has been received and entered.

Specification

4. The specification is objected to because of the following informalities:
The specification is objected to because the priority information is missing from the first page of the instant specification and the title is not representative of the invention.

Correction is required.

Abstract Objection

5. The abstract is objected to because of the following informalities:

In line 5 of the abstract the following inconsistency appears, "rpos and Rpos".
The phrase should be lower case or capital in both instances.
Correction is required.

Claim Objection

6. Claims 14-15 are objected to because of the following informalities:

Claim 14 is objected to because it the acronym "DHCP" does not have the spelled out meaning.

Claim 15 is objected to because it the acronym "AI-2" does not have the spelled out meaning.

Correction is required.

Information Disclosure Statement

7. The Information Disclosure Statements filed on December 6, 2006, April 19, 2006, August 2, 2005, June 1, 2005 and September 7, 2004 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

New-Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claims 14-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Note that claim 14 is directed to a method of inhibiting an activity of an interspecies quorum-sensing inducer however, the method has no positive method steps. The method reports that the compound DHCP (4,5-dihydroxy-2-cyclopenten-1-one) is an active ingredient and that the auto inducer AI-2 is also involved, however, the methods of claims 14-15 are devoid of any method steps to indicate how the recited inducers are utilized in said inhibition. Without setting forth any steps involved in the process/method, results in an improper definition of a process and are not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14-15-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The instant invention is directed to a method of inhibiting an activity of an interspecies quorum-sensing inducer, wherein DHCP is used as an active ingredient and wherein the inducer is AI-2. The claims do not establish a specific activity that is inhibited, but instead is broadly drawn to "an activity". The specification at page 3 discloses that "the present invention provides a method for regulating a gene in a microorganism by contacting a microorganism, in which the gene is to be regulated, with DHCP and thereby regulating the gene in the microorganism. The gene to be

regulated includes genes responding to stress...Preferably, the gene is involved in quorum-sensing processes such as a result of switching on/off of a quorum-sensing circuit or of an activity of an interspecies auto inducer AI-2". Note that the specification does not specifically establish "an activity". Thus, the claims broadly read on any activity and neither the claims or the instant specification defines said activity.

Moreover, the claims do not set forth any positive method steps to accomplish the recited inhibition. Therefore, the recited method is inoperable. The methods do not delineate what role the recited active ingredient "DHCP" plays in the inhibition method or the nexus between said "DHCP" and "AI-2". The amount of experimentation required to practice the claimed invention is undue based on the lack of guidance provided in the claims and the instant specification with respect to the activity to be inhibited and the missing method steps to accomplish the method objective. One of ordinary skill in the art would not be able to practice the method commensurate in scope with the claims; therefore this is merely an invitation for an ordinary skilled artisan to engage in undue experimentation. Furthermore, the claimed invention is unpredictable since it appears that the recited inducer (AI-2) is not well established in the art based on the disclosure in the specification at page 2 lines 29-30 (see "AI-2 is used for interspecies communication and its structure is not known).

The state of the prior art provides evidence for the high degree of unpredictability as stated above. The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed invention. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to practice the claimed invention commensurate in scope with the claims.

The specification does not provide support for the broad scope of the claims as indicated above. The claims broadly read on "any activity" and "method steps". The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art. Therefore, applicants have not provided sufficient guidance to enable one of

skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: for example a "contacting step" to facilitate inhibition.

Claim 14 is indefinite because there is no nexus between the active ingredient and the recited method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Surette et al.(PNAS, 1998, vol. 96, pages 1639-1644), based on a method absent method steps.

Surette et al. teach that in bacteria the regulation of gene expression is called quorum sensing (see abstract). The reference also teaches that bacteria produce, release and respond to hormone like molecules called inducers (i.e.AI-2 found in *E. coli*). Thus the reference teaches the same bacteria, regulation of gene expression and the same inducer, therefore, the recitation of a compound is an inherent property. Therefore, the limitations of the claims are met by the reference.

Conclusion

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Primary Examiner

HOPE ROBINSON
PRIMARY EXAMINER